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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,521	02/18/2005	Gideon Schreiber	05558.0018.PCUS00	7709

22930 7590 10/17/2006  
HOWREY LLP  
C/O IP DOCKETING DEPARTMENT  
2941 FAIRVIEW PARK DR, SUITE 200  
FALLS CHURCH, VA 22042-2924

EXAMINER
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SAJJADI, FEREYDOUN GHOTB

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Advisory Action**  
**Before the Filing of an Appeal Brief**

Application No.

10/500,521

Applicant(s)

SCHREIBER, GIDEON

Examiner

Fereydoun G. Sajjadi

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**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 28 September 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: \_\_\_\_\_.
- Claim(s) objected to: \_\_\_\_\_.
- Claim(s) rejected: 62,66-71,75-83 and 85.
- Claim(s) withdrawn from consideration: \_\_\_\_\_.

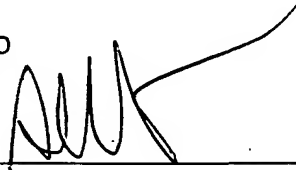
**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Attachment to Advisory Action.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_
13. ☐ Other: \_\_\_\_\_.

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER



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**Attachment to Advisory Action****10/500,521**

Continuation of 11: The Examiner maintains the rejection of claims 62, 66-71, 75-83 and 85 under 35 USC 112, first paragraph, written description and enablement; and 35 USC 103, for reasons of record. Applicant disagrees with the rejection of the claims, arguing that the IFNAR2 $\beta$ S and  $\beta$ L subunits have identical extracellular domains. Applicants arguments have been fully considered, but not found persuasive, as the claims as amended continue to read on other alternatively spliced forms of IFNAR2, including membrane bound and cytoplasmic forms. The fact that they may share the same extracellular domain as the soluble fom of IFNAR2 does not negate the fact that membrane bound and cytoplasmic forms are structurally and functionally distinct from that of the soluble forms. Hence, the written description rejection of the claims is maintained.

Regarding the rejection of claims 62-65, 67-83 and 85, as lacking an enablement for the full scope of the invention, Applicants state that the Examiner has based his rejection on the numerous variants of type I IFN receptors and reminds the Examiner that the claims are directed to IFNAR2 polypeptides through which IFN $\beta$  interaction is mediated, and not to type I IFN receptors. Such is not found persuasive, Applicants attention is drawn to page 1, paragraph [0003] of the their amended specification that states: type I interferons include interferon  $\alpha$ , interferon  $\beta$  and interferon  $\omega$ , while type II interferon includes interferon  $\gamma$ . IFNAR 2 is the beta subunit or beta chain of the receptor (p. 2, paragraph [0006]. In addition, the aforementioned issues regarding receptor types also apply to this rejection.

Regarding the rejection of claims 83 and 85 for lack of enablement, Applicants argue that the specification provides an adequate and specific teaching for what constitutes a sufficient amount of IFNAR2 to be administered for curative activity, and that that the ordinary artisan can calculate a concentration of mutated IFNAR2 to be administered. Such is not found persuasive, because Applicants have failed to address the issues set forth in the final office action, regarding the combined administration of the receptor and an IFN antagonist, in the context of their different properties as protagonist and antagonist. Thus the rejection of the claims is maintained.

In regards to the rejection of claims 62-81, under 35 USC 103, Applicants disagree with the rejections, arguing that the examiner has not taken into account secondary considerations of

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non-obviousness, such as unexpected results. However, the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP§716.01(c) <[http://www.uspto.gov/web/offices/pac/mpep/documents/0700\\_716\\_01\\_c.htm](http://www.uspto.gov/web/offices/pac/mpep/documents/0700_716_01_c.htm)> for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration. Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. MPEP 716.01(c). Applicant's assertion that such evidence is disclosed in paragraph [0014] of the instant specification is not found persuasive, because paragraph [0014] teaches that mutation H78A was found to stabilize the complex with IFN $\beta$  nearly by two fold and mutation N100A decreased the dissociation rate constant for IFN $\beta$  by almost four fold (i.e. increased stability and binding). Any effect of the mutations on destabilizing complexation with IFN $\alpha$ 2 are not relevant to IFN $\beta$ , that is the subject of instantly claimed binding. As there is no evidence in paragraph [0014] to suggest an absence of synergy between the two mutations for increasing IFN $\beta$  binding, and no evidence of unexpected results has been provided in an affidavit or declaration, these arguments are not persuasive. Therefore, the rejection of the claims is maintained.

Fereydoun G. Sajjadi, Ph.D.  
Examiner  
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